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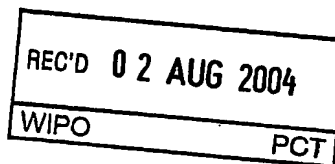
July 28, 2004

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FILING DATE: August 26, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/19491



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PATENT APPLICATION SERIAL NO. \_\_\_\_\_

U.S. DEPARTMENT OF COMMERCE  
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FEE RECORD SHEET

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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

| INVENTOR(S)  |  |   |                |  |                |
|--|--|---|----------------|--|----------------|
| Given Name (first and middle (if any))   |  | Family Name or Surname  |                | Residence<br>(City and either State or Foreign Country)                              |                |
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| <input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto                            |  |   |                |  |                |
| TITLE OF THE INVENTION (280 characters max)  |  |   |                |  |                |
| TWIST-SET NEEDLELESS INJECTOR  |  |   |                |  |                |
| Direct all correspondence to:  |  |   |                |  |                |
| <input checked="" type="checkbox"/> Customer Number  |  | CORRESPONDENCE ADDRESS  |                |  |                |
| 26822  |  |  |                |  |                |
| OR   |  | Type Customer Number here   |                |  |                |
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|  |  | Telephone   | (949) 851-5010 | Fax  | (949) 762-1925 |
| ENCLOSED APPLICATION PARTS (check all that apply)  |  |   |                |  |                |
| <input checked="" type="checkbox"/> Specification  |  | Number of Pages   | 6              | <input type="checkbox"/> CD(s), Number   |                |
| <input checked="" type="checkbox"/> Drawing(s)   |  | Number of Sheets  | 3              | <input type="checkbox"/> Other (specify)   |                |
| <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76   |  |   |                |  |                |
| METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)   |  |   |                |  |                |
| <input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees  |  |   |                | FILING FEE AMOUNT (\$)   |                |
| <input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: |  | 08-0114   |                | \$160.00   |                |
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| The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.          |  |   |                |  |                |
| <input checked="" type="checkbox"/> No.  |  |   |                |  |                |
| <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____                               |  |   |                |  |                |

Respectfully submitted,

SIGNATURE



Date

08/26/2003

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(if appropriate)

Docket Number:

3034P

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P18LARGE/REV05

TWIST-SET NEEDLELESS INJECTOR

A twist-set needleless injector in accordance with the present invention generally includes a housing having a proximal and a distal end. A chamber is disposed within the housing at the distal end thereof and an injector head is disposed at the housing distal end and in fluid communication with the chamber. A vial is provided for containing a medicament with the vial being in fluid communication with the chamber through a one-way valve.

A piston is slidably disposed within the housing and includes a piston head slidably disposed within the chamber and a stem disposed in the housing proximal end. The piston head is fitted to the chamber in order to draw medicament from the vial into the chamber through the one-way valve upon movement of the piston from a first position to a second position and to force medicament through the injection head upon movement of the piston from the second position to the first position.

A spring is provided and may be disposed around the piston stem for forcing the piston from the second position to the first position.

The spring is compressed by a rotatable grip which is threadably disposed at the housing proximal end and a sear is provided for releasably holding the piston in the second position with the spring compressed.

A trigger disposed in an operational relationship with the sear is provided for releasing the spring in order to drive the piston to the first position and force medicament through the injection head.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be more clearly understood with reference to the appended drawings of which:

Figure 1a is a perspective view of a twist-set injection in accordance with the present invention generally showing a housing, an injection head, a rotatable grip and a trigger;

15

Figure 1b is a plan view of the injector shown in Figure 1 partially broken away to illustrate a vial for containment of a medicament, a piston, a one-way valve, a mainspring, and a check valve;

20

Figure 2 is a cross sectional view of the injector shown in Figures 1a and 1b more specifically showing a chamber disposed within the housing, a piston slidably disposed within the housing with a piston head fitted within the chamber, and having a stem with a spring disposed therearound along with a sear for holding the piston in a second position with the spring compressed;

Figure 3 is a cross sectional view similar to Figure 2 showing release of the piston with the spring forcing the piston head through the chamber in order to force medicament through the injection head; and

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Figure 4 is a cross sectional view similar to Figures 2 and 3 showing cocking of the spring and withdrawal of medicament from the vial into the chamber for subsequent injection by rotation of the grip.

10

#### DETAILED DESCRIPTION

With reference to Figures 1a and 1b, there is shown a twist-set needleless injector 10 generally including a housing 12, an injection head 14, a vial 16 for containing a medicament, such as, for example, BOTOX®, a rotatable grip 20 and a trigger 22.

As shown in Figures 2-4, the housing 12 includes a distal end 26 and a proximal end 28 with a chamber 30 disposed within the housing 12 at the distal end 26.

The injection head 14, which may be of conventional design, is disposed at the housing distal end 26 and is in fluid communication with the chamber 30.

The vial 16 may support a replaceable container 34 containing a medicament, not shown, as hereinabove referenced

and is in fluid communication with the chamber through a dip tube 36 and a one-way valve 38, for example a duckbill valve.

5 A piston 40 is slidably disposed within the housing 12 and includes a piston head 42 slidably disposed within the chamber 30 and a moveable stem 44 disposed in the housing 12. The piston head 42 is fitted within the chamber 30 in order to draw medicament from the vial 16 into the chamber 30 through the one-way valve 38 and dip tube 36 upon movement of the  
10 piston head from a first position, as shown in Figure 3, to a second position shown in Figure 4 the entry of fluid into the chamber being indicated by the arrow 50 in Figure 4.

Medicament is forced through the injection head 14 by  
15 movement of the piston head 42 from the second position, as shown in Figure 3, to the first position as shown in Figures 2 and 4 with the injected medicament being indicated by the arrow 52. A head 54 on the piston stem 44 couples the stem 44 in a slidable manner with the piston head 42 between a fore  
20 plate 60 and an aft plate 62.

As shown in Figures 2-4, a spring 66 disposed around the piston stem 44 between the aft plate 62 and an end plate 70 which is compressed by the rotating grip 20 which is  
25 threadably disposed at the housing proximal end 28. Rotational movement of the cocking grip causes compression of the spring 66, as illustrated in the figures. A sear 74 is provided for releasably holding the piston 44 in the second

position with the spring 66 compressed by engagement with the aft plate 62, as shown in Figure 2.

5 The trigger 22 is pivotally 76 disposed on the housing 12 and in an operational relationship with the sear 74 for releasing the spring 66 in order to drive the piston 42 along with fore plate 60 to the first position, thus ejecting a metered dose of medicament determined by the chamber 30 volume.

10

Although there has been hereinabove described a specific push-pull needleless injector in accordance with the present invention for the purpose of illustrating the manner in which the invention may be used to advantage, it should be  
15 appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element which is not  
20 specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be within the scope of the present invention as defined in the appended claims.

25



ABSTRACT

A twist-set needleless injector includes a housing having a distal and a proximal end, a chamber disposed within the housing at the distal end thereof and an injection head disposed at the housing distal end and in fluid communication with the chamber. A vial is provided for containing a medicament, the vial being in fluid communication with the chamber through a one-way valve. A piston is slidably disposed within the housing and includes a piston head slidably disposed within the chamber and a stem disposed in the housing proximal end, the piston head being fitted to the chamber in order to draw medicament from the vial into the chamber through the one-way valve upon movement of the piston from a first position to a second position and to force medicament through the injection head upon movement of the piston from the second position to the first position. A spring disposed around the piston stem is provided for forcing the piston from the second position to the first position and a rotatable grip threadably disposed at the housing proximal end for compressing the spring. A sear is provided for releasably holding the piston in the second position with the spring compressed and a trigger is disposed in an operational relationship with the sear for releasing the spring in order to drive the piston to the first position.



TwistSet Needleless Injector

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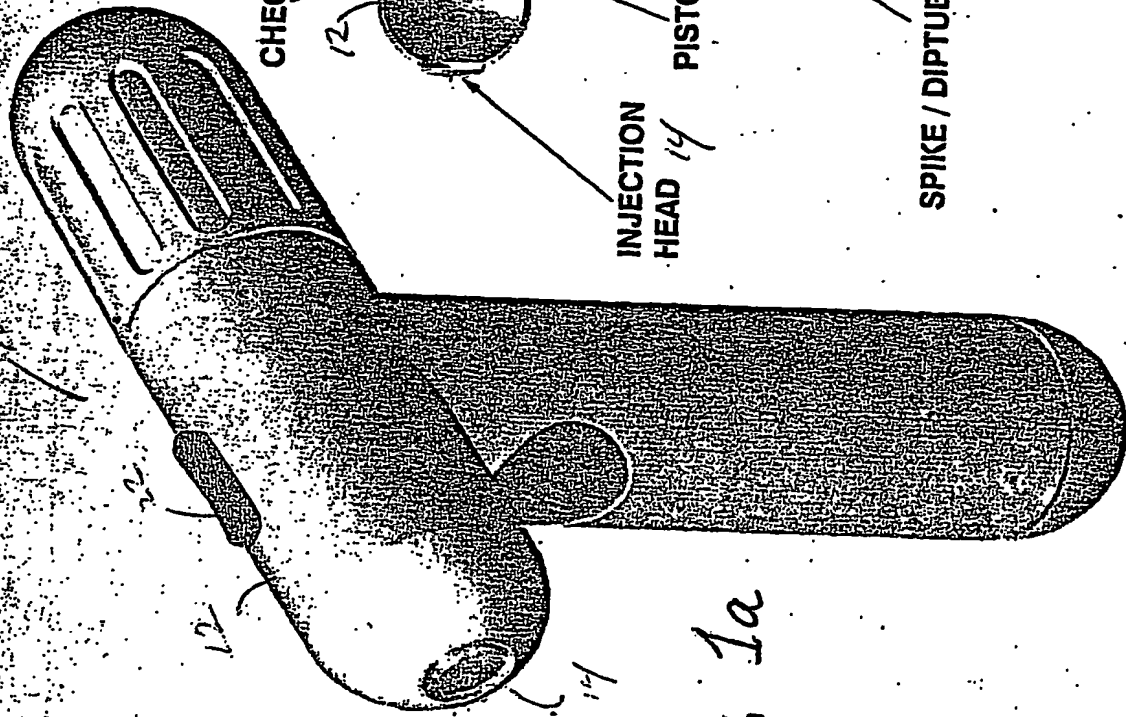


FIG 1a

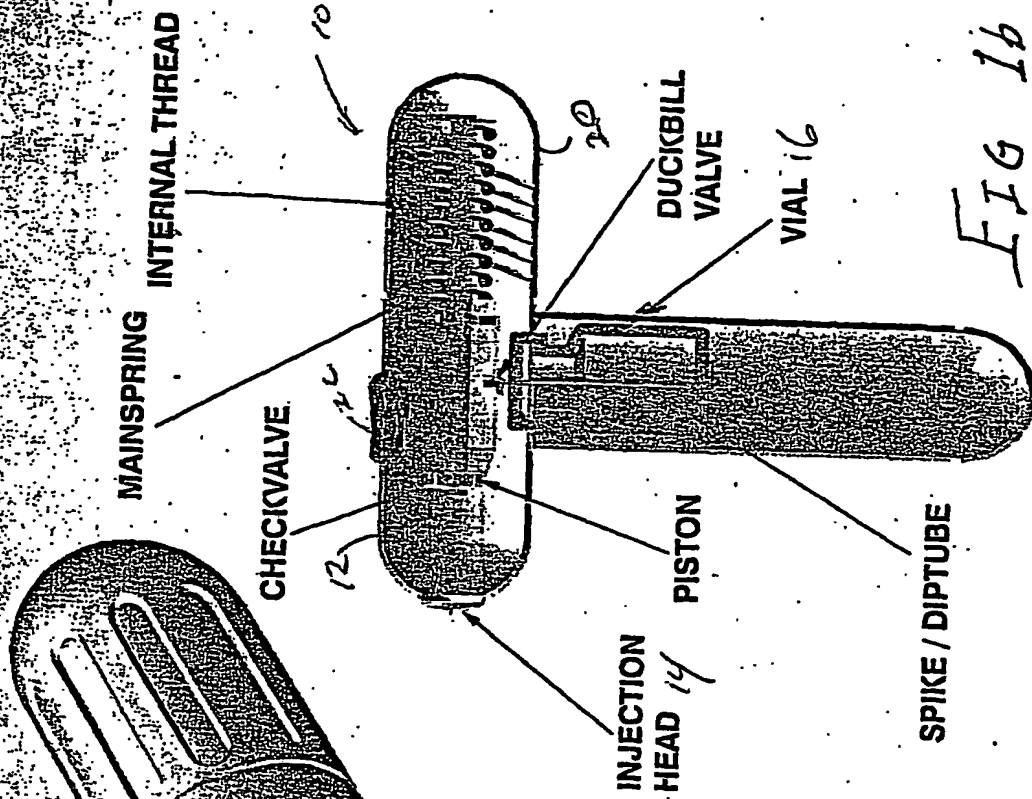
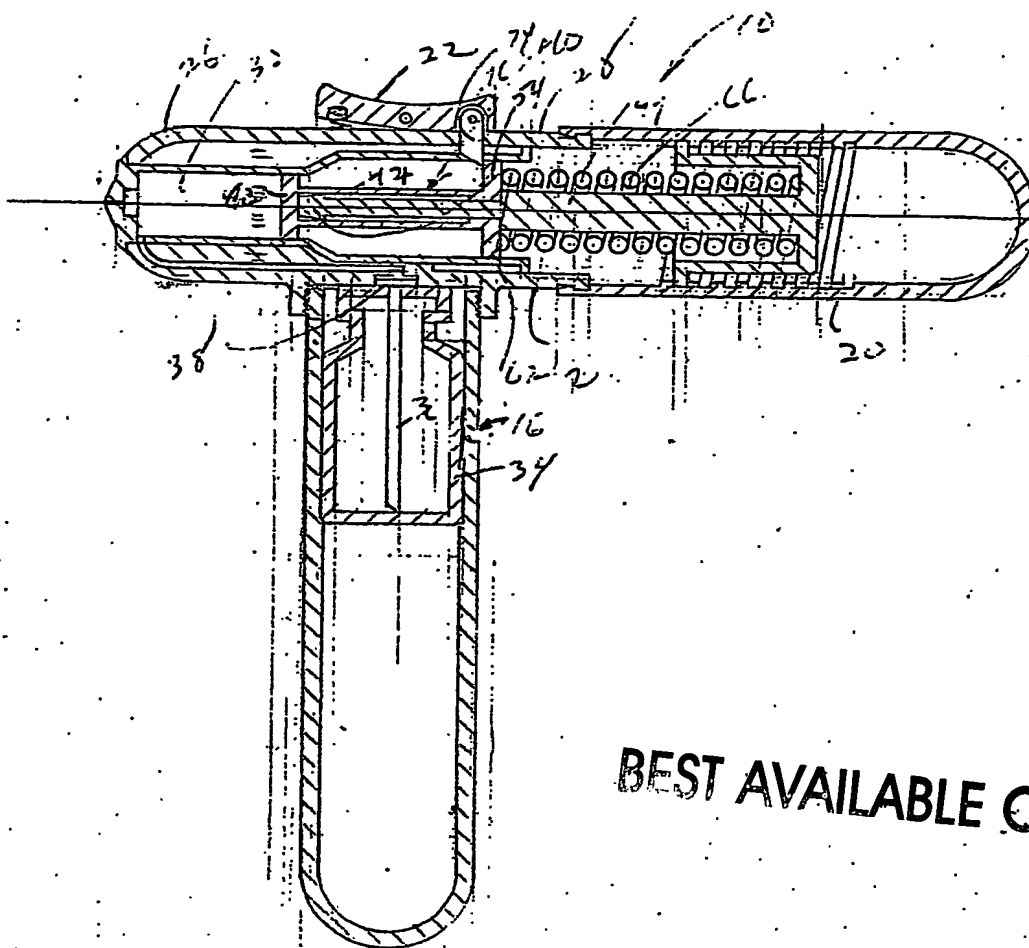


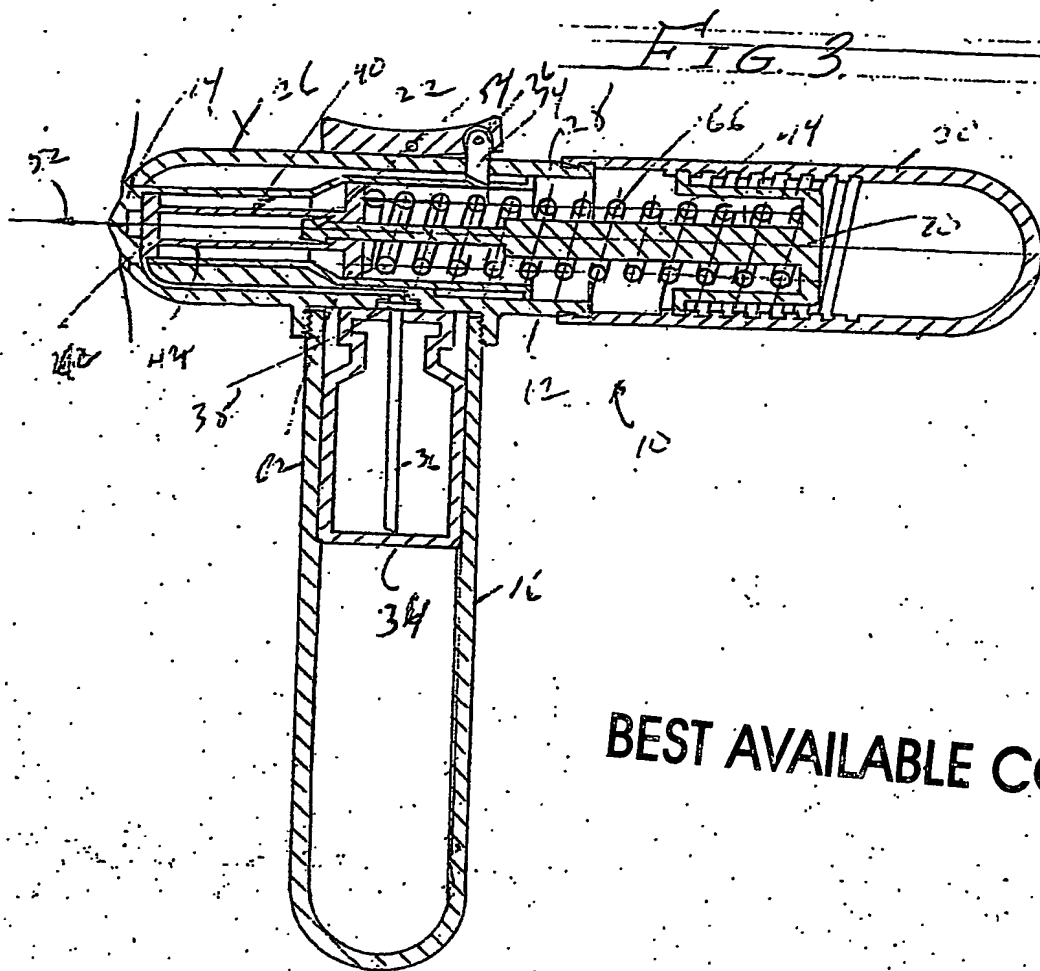
FIG 1b

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FIG. 7



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